

AUG 15 1996

3. SAFETY AND EFFECTIVENESS SUMMARY

The Following is a summary of the safety and effectiveness of the Endocare Electronic Thermometer System.

1.0 General Information:

Device Name: Endocare Electronic Thermometer System

Manufacturer: Endocare Inc.

Sterilizer: Sterigenics International

2.0 Description

Temperature monitoring systems have been in the medical device market place for several decades. Endocare is introducing an Electronic Thermometer System that incorporates a flexible user interface for easy of use. The Temperature Monitoring System can be used with a variety of thermocouple probes. The probes can be used for intra-operative temperature monitoring to avoid unintended tissue damage.

3.0 Substantial Equivalence Support

The Endocare Electronic Thermometer System are designed for use in General Surgery, Urology, and Gynecology to monitor tissue temperatures during thermotherapy, cryosurgery, or normal intra operative feedback.

The Endocare Electronic Thermometer System has the same temperature measuring characteristics as current electronic thermometer systems.

The Endocare Electronic Thermometer System is **substantially equivalent** to the Bailey BAT-8 clinical monitoring thermometers and the Electromedics TM147T Temperature Monitoring System. The Bailey BAT-8 clinical monitoring thermometers (Pre-Medical Device Amendments of 1976) and the Electromedics TM147T Temperature Monitoring System (K#830592A) have been granted market clearance by the FDA .